PSJ3

Exhibit 529

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Suspicious Order Monitoring (SOM)

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DEA Expectations

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"DEA regulations require wholesale distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system...Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."

"Registrants that fill these orders (potential suspicious orders), without first determining that the order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate or Registration."

December 2007 letter from DEA

Reference: http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm

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Penalties Levied by DEA

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Walgreens

- **June 2013** – paid $80 million in fines to end a DEA probe into allegations it allowed millions of controlled substances, including oxycodone, to reach the black market.
- **September 2012** - DEA Registration suspended until September 2014 in their Jupiter, FL distribution center due to lack of a controls of monitoring sales of controlled substances and six of its Florida pharmacies until May 2014.

Cardinal Health

- **February 2012** - DEA Registration suspended for 2 years in FL distribution center because of sales of Oxycodone to 4 pharmacies in FL (2 CVS's, DEA Permit Suspended).
- **In 2008** - paid $34 million in fines to settle charges that it failed to report suspicious orders of hydrocodone by pharmacies operating on the Internet. Cardinal's conduct allowed "the diversion of millions of dosage units of hydrocodone from legitimate to non-legitimate channels," the DEA said.
- **November 2007** - the DEA Registration suspended for their Auburn, Wash., distribution facility for selling 18 million hydrocodone pills in nine months to retail drugstores. The company sold 805,000 pills to one store in Burlington, Wash., over a seven-month period, the DEA said.
- **December 2007** - the DEA Registration suspended for their Lakeland distribution center for selling large amounts of controlled substances, particularly hydrocodone, to illegal Internet pharmacies.
- **August 2005** - DEA officials had warned Cardinal about its excessive sales of hydrocodone drugs, such as Vicodin, to online pharmacies filling illegal prescriptions.

AmerisourceBergen

- **April 2007** - Temporarily had DEA registration suspended for their Florida distribution center.
- The DEA claimed AmerisourceBergen did not maintain effective controls against diversion of controlled substances.
- Settlement undisclosed.

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Penalties Levied by DEA

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Keysource Medical
- **April 2012** - Temporarily had DEA registration suspended for shipments of suspicious orders and paid $320,000 in fines

Sunrise Wholesale, Inc.
- **June 2010 –** Surrendered DEA License

Harvard Drug Group
- **June 2010** - Temporarily had DEA registration suspended for shipments of suspicious orders and paid $8 million in fines

McKesson
- **May 2008** - Temporarily had DEA registration suspended for failing to report a suspicious order and paid $13.25 million in fines

Bellco Drug Corporation
- **July 2007** - Paid $800,000 in fines for not reporting suspicious orders and surrendered its DEA registration

Southwood Pharmaceutical Inc.
- **December 2006 -** DEA registration permanently suspended for shipping suspicious orders

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Keys to an Effective SOM Program

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Know Your Customer

- The DEA expects registrants to "Know Your Customer" and even to Know Your Customers, Customer…No order should be released unless the team is comfortable that it is for legitimate purposed.

Documentation

- All correspondence with the field and other business partners that pertain to either clearing or blocking a flagged order must be documented in detail in case ever questioned by the DEA.
- Any information that is looked at outside of the SOM Algorithm output must be referenced/documented if it is used to determine the legitimacy of an order.
- Once an order is determined to be Suspicious or whether it is deemed that the order is legitimate, it is important that we document how we came to that decision.
- All communications and discussions with the DEA, local law enforcement, and State Boards of Pharmacy must be documented in detail.
  - Any requests for information from state and government agencies must be done so in writing.

Detailed Policies and Procedures

- The DEA expects companies to have detailed policies and procedures that are documented and available for review during on site inspections.
  - **IMPORTANT:** If it is documented in our SOP's, it is essential that we execute as written in the policies and procedures.

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Keys to an Effective SOM Program (Cont.)

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Consistency

- It is important that the team is consistent in the way we approach the due diligence process and our decision making process.
  - If we are investigated by the DEA and they are reviewing our Archer Application and various records, it is important that there is consistency in our thought process when reviewing orders. This will limit the questions around why some orders were released in some cases but not others.

Communication

- Because the SOM process effects many of our internal business partners (The Field, DC Operations, Pharmacy Ops, Loss Prevention, Compliance, Legal…) it is important that there are open lines of communication between all involved parties.
  - Effective communication will prevent duplicating work when there are investigations already ongoing in some cases, and will also lead to streamlining the due diligence process allowing the team to review and close cases in a more timely manner.

Not Just a Systematic Approach

- Although the SOM Algorithm is an essential piece to an effective SOM Program, it cannot solely be relied on in identifying potentially suspicious activity in our customers (Retail Pharmacies) practices.
  - Other ways to identify stores that should be looked at closer and require additional due diligence is by reviewing our ARCOS Reports and reviewing our highest ordering stores via sales reporting.
    - ARCOS reports only include schedule III controlled substances. Schedule IV-V controlled substances would need to be obtained though separate data runs.

DEA Reporting Requirements

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CVS is obligated to report identified Suspicious Orders **placed to our Distribution Centers** to the DEA within 24 hours of the determination being made.

- Only orders of controlled substances need to be reported to the DEA.
  - Any store who has an order identified as suspicious will not be allowed to order the suspicious drug family again until remediation plans are developed and implemented.
  - Some drugs are only considered controlled substances in certain states, these drugs do not need to be reported to the DEA.
- Orders deemed Suspicious will be reported to the Local DEA of the ordering store via certified letter.
- Orders that are placed to an Outside Vendor that we identify as an order deviating from the normal size, frequency, and/or buying pattern and deem the order to not be for legitimate purposes are not required to be reported to the DEA.

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Key Takeaways

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- **DOCUMENTATION, DOCUMENTATION, DOCUMENTATION!!!**
  - Documenting all activities that lead to the disposition of an order is key to a defensible SOM Program. If it is not documented, it was not done.
- **You are protecting each Distribution Centers DEA Registration**
  - It is important to remember that your responsibility is to obtain and document as much information as possible to address all identified "Red Flags." If all "Red Flags" cannot be resolved adequately, we cannot release the order.
    - ✓ Just because the Pharmacist says the order is legitimate, does not mean that it is.
- **The DEA will follow up on Suspicious Orders**
  - Do not volunteer any information to the DEA, only provide information to answer the question that is asked.
  - Nothing said is off the record…
  - If you do not know the answer to any question, do not guess…it is OK to let the investigator know you will need to look into something more and get back to them.
  - Before any information can be released to the DEA, we must obtain the request in writing and have it reviewed by our Legal Department.
- **Orders that are deemed as Suspicious must be reported within 24 hours**
  - Orders that are flagged by the SOM Algorithm are "Orders of Interest" until we complete the due diligence process and are unable to determine its legitimacy.

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